K121854

AUG 2 2 2012

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: Mar 10. 2012

2. Sponsor
   Beijing Sinopharm Hundric Mediline Info. Tech. Co., Ltd
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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: Digital X-ray Radiography System
   Proposed Device Model: Eagle-DR2000A
   Classification: II
   Product Code: KPR
   Regulation Number: 21 CFR 892.1680
   Review Panel: Radiology

Intended Use Statement:

The Digital X-ray Radiography System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

5. Predicate Device Identification

510(k) Number: K012389
Product Name: Revolution XR/d Digital Radiographic Imaging System
Manufacturer: GE Medical System

6. Device Description

The Digital X-ray Radiography System is indicated for use in generating radiographic image of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

The Digital X-ray Radiography System is designed to perform radiographic X-ray examinations. It consists of a control cabinet, a high voltage (HV) generator, an X-ray source assembly including an X-ray tube and an collimator, an Overhead Tube Suspension, a amorphous silicon (a-Si) detector, an elevating radiographic Table, a radiographic wall stand unit and a workstation.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC60601-1+A1+A2:1988 Medical Electrical Equipment- Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment2, 1995

IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests

CFR 1020.30 Performance Standards for Ionizing Radiation Emitting Products

CFR 1020.31 Radiographic equipment

IEC 60601-2-7 (1998) Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

IEC 60601-1-3: 1994, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

IEC 60601-2-28: 1993, Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

IEC 60601-1-1:2000, Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.

IEC60601-2-32:1994, Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment - Ed. 1.0.

ISO 10993-5:2009 Standard, "Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity"

ISO 10993-10:2010 Standard: Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization

8. Substantially Equivalent Conclusion

The proposed device, Digital X-ray Radiography System, is determined to be Substantially Equivalent (SE) to the predicate device, Revolution XR/d Digital Radiographic X-ray System (K012389). in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Beijing Sinopharm Hundric Mediline Info. Tech. Co., Ltd.
% Ms. Diana Hong
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SHANGHAI 200030
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AUG 2 2 2012

Re: K121854
Trade/Device Name: Digital X-ray Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 21, 2012
Received: June 25, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section II Indications for Use

510(k) Number:
Device Name: Digital X-ray Radiography System

Indications for Use:

The Digital X-ray Radiography System is indicated for use in generating radiographic image of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510k 5/21/854